12/10/98
MRG

Public Health Service
DEPARTMENT OF HEALTH AND HUMAN SERVICES
HFI-35
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-06

November 9, 1998

Osmany Padilla, Owner
Duke's Transport
7101 N.W. 77th Terrace
Medley, Florida 33166

Dear Mr. Padilla:

On August 31 and September 2 and 11, 1998, the Food and Drug Administration (FDA) conducted an inspection of your fish storage warehouse. The investigator documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123) causing fresh tuna being received and stored by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

Failure to follow the monitoring procedures specified in your written HACCP plan for receiving and storage of histamine producing fish [21 CFR 123.6(b)].

Failure to maintain records documenting the monitoring of the critical control points specified in your written HACCP plan [21 CFR 123.6(c)(7)].

Failure to take appropriate corrective action when a critical limit listed in your written HACCP plan was exceeded. For example, your plan specifies that no histamine producing fish will be accepted by your firm if the temperature at receiving is greater than 45° F. On September 2, 1998, the temperature of a large tuna was found to be 48° F upon receipt using a calibrated thermometer. No corrective action was taken and the tuna was accepted and placed in storage [21 CFR 123.7(b)].

Failure to maintain sanitation control records [21 CFR 123.11(c)] that document the monitoring and corrections during receiving and storage of all sanitation conditions specified in the regulations, for example, plant water (ice) safety, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions, and exclusion of pests [21 CFR 123.11(b)].

In addition, the seafood regulations require that you have and implement a written HACCP plan specific to each kind of fish and fishery product received and stored by your firm to control various types of potential food safety hazards that are reasonably likely to occur. We note that your current single written HACCP plan groups multiple species of fish with different potential hazards together. A HACCP plan may group kinds of fish together only if the potential hazards, critical control points, critical limits, and control procedures are identical [21 CFR 123.6(b)].

We acknowledge receipt of a letter, dated September 29, 1998, from Judith Lobo Padilla, submitted to this office in response to the list of observations (Form FDA 483) issued at the conclusion of our inspection. It is unclear from this response that a written HACCP plan specific to each kind of fish product received and stored by your firm has been implemented. Also, no examples of your revised HACCP plan, monitoring records, sanitation records, temperature logs, or other documentation was included to support the stated corrective actions. This response does not alleviate our concerns regarding the observations made during the inspection.

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your storage warehouse. It is your responsibility to ensure that all fish products received, stored, and distributed by your firm are in compliance with the Act and the requirements of the regulations.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any fish products received and stored by your firm until compliance with the seafood regulations is achieved.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District